

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
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NOV 4 2002

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Contact: Wendell Lee, Pharm. D.

Date Submitted: October 9, 2000

Device Identification:

Trade Name: Hyaluronidase Solution
Common Name: Hyaluronidase Solution
Classification Name: Reproductive Media (21 CFR, 884.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Description:

Hyaluronidase Solution is a enzymatic solution containing 80 U/mL of bovine derived hyaluronidase in a HEPES buffered HTF Medium supplemented with 5.0 mg/mL (or 0.5%) therapeutic grade human serum albumin (HSA) and 10µg/mL gentamicin sulfate.

Intended Use:

Hyaluronidase Solution is intended for use in removing cumulus cells surrounding oocytes (denudation) in preparation for ICSI or other ART procedures.

Technological Characteristics:

Enzymatic digestion and removal of cumulus cells surrounding freshly retrieved oocytes will occur within a 30 – 60 second exposure to Hyaluronidase Solution. Denuded oocytes should be immediately washed and transferred to appropriate medium for subsequent fertilization (by ICSI) and ongoing development.

Performance Data:

Hyaluronidase Solution is assayed by mouse embryo assay prior to its release to market. This assay assures that the product will support embryonic growth and that no toxic components are present. The equivalent of Hyaluronidase Solution has been used in a variety of clinical settings for the same intended use for a number of years and has become the standard medium used for denuded oocytes.

Additional Information:

Mouse Embryo Assay, enzyme activity, endotoxin and sterility testing will be performed as a condition of release for this product. Results of all release assays performed will be indicated on the labeling and reported on a lot-specific certificate of analysis.

Conclusion:

The conclusion from performance testing as well as a review of the historical information contained in professional literature shows that Hyaluronidase Solution is suitable for the intended use and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Wendall Lee, PharmD
Vice President
Quality Systems and Regulatory Affairs
Irvine Scientific Sales Co., Inc.
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SANTA ANA CA 92705-5588

Re: K022931
Trade/Device Name: Hyaluronidase Solution
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media
and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: August 23, 2002
Received: September 4, 2002

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

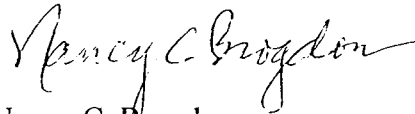
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K022931Device Name: Hyaluronidase Solution

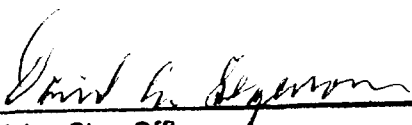
Indications for Use:

Hyaluronidase Solution is intended for use in assisted reproductive technology procedures involving the manipulation of gametes or embryos. Specifically, Hyaluronidase Solution is intended for use in removing cumulus cells surrounding oocytes (denudation) in preparation for ICSI or other ART procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022931